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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,440	03/17/2004	Martha Karen Newell	V0139.70060US01	4035

7590 03/31/2006
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EXAMINER

VANDERVEGT, FRANCOIS P

ART UNIT PAPER NUMBER

1644

DATE MAILED: 03/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/802,440	Applicant(s) NEWELL, MARTHA KAREN	
	Examiner F. Pierre VanderVegt	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>08182005</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

This application is a continuation of U.S. Application Serial Number 09/711,022; which is a continuation of U.S. Application Serial Number 09/277,575, which claims the benefit of the filing date of provisional applications 60/082,250; 60/094,519 and 60/101,580.

Claims 1-11 are currently pending and are the subject of examination in the present Office Action.

Specification

1. The use of the trademark ADRIAMYCIN has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. ADRIAMYCIN is a trademark for the chemotherapeutic agent doxorubicin hydrochloride. ADRIAMYCIN has been found recited in claim 2, for example.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

Applicant should review the remainder of the specification for additional occurrences of trademark names and correct the specification accordingly.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5, and 7-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Posada et al (Cancer Comm. [1989] 1(5):285-292; U on form PTO-892).

Posada teaches the induction of apoptosis in multi-drug resistant human KB tumor cells by simultaneous local contact of the cells with a combination of the metabolic modifying agent staurosporine and the apoptotic chemotherapeutic agent ADRIAMYCIN (Abstract in particular), a trademark for doxorubicin hydrochloride, an anthracycline antibiotic used for cancer chemotherapy that targets actively dividing cells. Posada is silent regarding whether staurosporine increases the mitochondrial membrane

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potential of the tumor cell, however silence about a particular property does not necessarily constitute its absence. It is noted that the claim does not recite the degree to which the metabolic modifying agent raises mitochondrial membrane potential, so even the tiniest amount of an increase would satisfy the metes and bounds of the claim. The assertion in the claim that mitochondrial membrane potential is increased appears to merely constitute a further characterization of an otherwise old property of the metabolic modifying agent. Accordingly, absent a showing to the contrary or a recitation in the claim of a degree of increased mitochondrial membrane potential not realized by the prior art, the amount of staurosporine administered to the tumor cells by Posada is reasonably assumed to increase mitochondrial membrane potential to at least a minimal degree and therefore satisfies the metes and bounds of the claim. The prior art teaching anticipates the claimed invention.

3. Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Fanciulli et al (Oncology Res. [1996] 8(3):111-120; V on form PTO-892).

Fanciulli teaches the treatment of ADRIAMYCIN-sensitive [claim 6] and ADRIAMYCIN-resistant [claims 5 and 11] MCF-7 human breast cancer cells with simultaneous local contact with a combination of the metabolic modifying agent glucose and the apoptotic chemotherapeutic agent ADRIAMYCIN (Abstract in particular), a trademark for doxorubicin hydrochloride, an anthracycline antibiotic used for cancer chemotherapy that targets actively dividing cells. Fanciulli is silent regarding whether glucose increases the mitochondrial membrane potential of the tumor cell, however silence about a particular property does not necessarily constitute its absence. It is noted that the claim does not recite the degree to which the metabolic modifying agent raises mitochondrial membrane potential, so even the tiniest amount of an increase would satisfy the metes and bounds of the claim. The assertion in the claim that mitochondrial membrane potential is increased appears to merely constitute a further characterization of an otherwise old property of the metabolic modifying agent. Accordingly, absent a showing to the contrary or a recitation in the claim of a degree of increased mitochondrial membrane potential not realized by the prior art, the amount of glucose administered to the tumor cells by Fanciulli is reasonably assumed to increase mitochondrial membrane potential to at least a minimal degree and therefore satisfies the metes and bounds of the claim. The prior art teaching anticipates the claimed invention.

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Conclusion

4. No claim is allowed.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D.
Patent Examiner
March 20, 2006

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
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